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November 1, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane,
Room. 1061
Rockville, MD 20852.

Dear Dr. Michael Kashtock :

This letter is in response to Docket Number 02D-0333, "Juice HACCP Hazards and Controls Guidance, First Edition, Draft Guidance", which was released for public comment on September 12, 2002. The comments submitted here reflect your recent advice to us to focus on information that would be meaningful to juice processors, in particular for those that are considering novel technologies for compliance to the Juice HACCP Regulation. The technology that we are addressing here is **dense phase carbon dioxide processing (DCO₂P)**. In the gas industry, supercritical and liquid CO₂ are known collectively as dense-phase CO₂ (5)

Researchers both in the US and worldwide have demonstrated that dense phase CO₂ is effective in reducing vegetative pathogens (2,4). Independent work using DCO₂P in pathogen challenge studies conducted by both the National Center for Food Safety and Technology (NCFST) and IIT Research Institute (IITRI) have validated the technology to achieve 5-7 log reductions on numerous pathogens in orange juice (7). DCO₂P is currently under consideration for commercialization by several juice processors here in the US and Europe.

We are requesting a new section for DCO₂P in V.C. 5.3. Current wording in the guidance document does not address this unique technology. DCO₂P is distinctly different from high pressure processing (HPP) in the following areas:

1. In DCO₂P the major anti-microbial agent for vegetative pathogens is carbon dioxide (2). Moderate pressure, 1200 – 5000 psig, is used to maintain the carbon dioxide in it's dense phase state (3,6). In HPP, pressure is the principal anti-microbial agent. To be effective in destroying vegetative pathogens processing pressure for HPP must exceed 30,000 to 45,000 psig (1,7).
2. CO₂ is a processing aid for the DCO₂P technology. The CO₂ is removed from the juice by mild vacuum at the final stage of the process prior to packaging. This differentiates DCO₂P from processes that incorporate CO₂ in sealed containers before HPP treatment. In such HPP processes CO₂ is not removed from the products and it may remain in the juice until consumed.

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3. DCO₂ P is a continuous process whereas HPP is limited to a cyclic semi-continuous or batch process.

We therefore propose the following amendments to the Draft Guidance document:

- 1) Make an addition to the draft guidance document in section V.C. 5.3 to include wording for dense phase carbon dioxide processing (Attachment 1).
- 2) Include dense phase CO₂ processing as an additional "Possible control measures" in Table 1 (Most Likely Hazards/Control Measures for Juice) of Section V.F (Attachment 2).

We may be contacted for further information at the address and phone numbers below.
Thank you for taking our input under consideration.

Sincerely,

A handwritten signature in cursive script that reads "Armand Paradis".

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A handwritten signature in cursive script that reads "Grace Ho".

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References

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